DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0120]

Medical Devices: Draft Guidance for Industry and FDA Reviewers; Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ‘‘Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns.’’ FDA has received many inquiries pertaining to multiplex test submissions (including microarray submissions). This draft guidance document represents the Center for Devices and Radiological Health’s (CDRH) attempt to continue the dialogue with stakeholders regarding the basic framework for the types of data that should be included in a submission. FDA is anxious to provide the best guidance possible to assist sponsors in developing multiplex text submissions that will support timely review and marketing of safe and effective products using this technology. This draft guidance document is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance document by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ‘‘Multiplex Tests for Heritable DNA Markers,

Mutations, and Expression Patterns'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

Submit written comments on this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield or Michele Schoonmaker, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

FDA anticipates that multiplex tests, including such as microarrays, using DNA and ribonuclei acid samples will are anticipated to have a number of clinical purposes, including genotyping, haplotype analysis, and categorization by expression profile, etc. FDA has received many inquiries pertaining to possible regulatory strategies for submitting and reviewing data from assays yielding multiple, simultaneous results. Over the past 24 months, FDA has participated in a number of seminars and workshops with representatives from

the drug and device industries, professional societies, laboratory professionals, healthcare providers, and other stakeholders, which discussed the criteria that are important in the analytical and clinical validation of multiplex assays. These discussions also explore the kind of information the industry might submit to the agency to achieve the least burdensome means of demonstrating substantial equivalence or evaluating effectiveness. FDA is issuing the draft guidance document in an effort to continue this dialogue. FDA believes the draft guidance document represents a summary of the discussions that have taken place.

FDA recognizes, however, that the discussions to this point have been introductory. Therefore, following review of the comments we receive on this draft guidance document, FDA intends to issue a new draft guidance document for additional discussion. FDA is taking this approach because we believe the public health will benefit from dialogue with the industry about appropriate ways to review this new and important technology.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control Number 0910–0120 and/or premarket approval applications (21 CFR part 814, OMB Control Number 0910–0231)).

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments. Submit two hard copies of any mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

To receive a copy of ‘‘Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns’’ by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1210) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved

applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information.

Dated: lllllllllll

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